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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,827	08/18/2006	Nicolas Mermod	GRT/2590-150	6727

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EXAMINER	
GUPTA, ANISH	
ART UNIT	PAPER NUMBER
1654	
MAIL DATE	DELIVERY MODE
03/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,827	MERMOD ET AL.	
	Examiner	Art Unit	
	ANISH GUPTA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 2-22-06.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 2-3, 5, 7-8, 10-11 and 13 provides for the use of "the protein", but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 2-3, 5, 7-8, 11 and 13 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to "use of protein[s]" as coagulant agents and antimicrobial agents. Assuming that the "use of" is intended to mean method of using the protein as coagulation agents

and antimicrobial agents, the specification states for these methods that "detailed description of the invention (e.g. material & method, experimental results) can be found in international patent application PCT/CH03/00568 which is incorporated by reference." (see page 2 of the specification). This means of incorporation, however, does not enabling disclosure for the claimed "use of" claims.

37 CFR 1.57(c) prohibits incorporation by reference to essential subject matter using international application. 37 CFR 1.57(c) recites:

> (c) " **Essential material** " may be incorporated by reference, but **only by way of an incorporation by reference to a U.S. patent or U.S. patent application publication,** which patent or patent application publication does not itself incorporate such essential material by reference. "Essential material " is material that is necessary to:
> (1) Provide a written description of the claimed invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and set forth the best mode contemplated by the inventor of carrying out the invention as required by the first paragraph of 35 U.S.C. 112;
> (2) Describe the claimed invention in terms that particularly point out and distinctly claim the invention as required by the second paragraph of 35 U.S.C. 112; or
> (3) Describe the structure, material, or acts that correspond to a claimed means or step for performing a specified function as required by the sixth paragraph of 35 U.S.C. 112."

First, the claimed subject matter is "Essential material" since it provide it provides written description as defined in sub paragraph (1). In order to practice the claimed invention, that to obtain the proper dosage, formulations, which microbes the peptides can be applied against, etc. . ., one is required to review PCT/CH03/00568. Without such guidance one of ordinary skill in the art use the peptide as a anticoagulant or antimicrobial agent, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and set forth the best mode contemplated by the inventor of carrying out the invention as required by the first paragraph of 35 U.S.C. 112. In essence, one would be burdened with undue experimentation to determine which fungus and microbial species the agent could be used against, how one of ordinary skill in the art would obtain the agent and the

proper dosage/mode of administration for the agent. Thus, the PCT/CH03/00568 is required to practice the claimed invention. Accordingly, the subject matter in PCT/CH03/00568 is essential.

The subject matter that is deemed essential is cited in PCT/CH03/00568, an international application. Since the "Essential material," claimed in the instant application, is not recited in a "U.S. patent or U.S. patent application publication, which patent or patent application publication does not itself incorporate such essential material by reference," it is improper to provide support via the "incorporation by reference" means.

Thus, claims lack proper written description since the specification improperly incorporate essential materials through an international application. The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 4-13 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 4, 6, 9, 12 recite sequences that are found in the seed extracts of Moigna oleifera lam, a tropical tree (see Suarez et al.). Since the claims do not recite "isolated" and "purified," the claims read on the peptide found in nature. A thing occurring in nature, which is substantially unaltered, is not a "manufacture." See MPEP 706.03(a).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 4-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Suarez (Biotech. & Bioengin.).

The claims are drawn to peptides and "use of" these peptides as coagulant and antimicrobial agents.

The reference disclose the peptide of the sequence *QGPGRQPDFQRCGQQLRNISPP***QRCPSLRQAVQLTHQQQGQV**GPQQVRQMYRVASNIP ST (see page 15 of the reference). This sequence meets the limitation of claim 4 since it contains the sequence RCGQQLRNISPPQRCPSLRQAVQLTHQQQGQ (see underlined portion). The reference meets the limitation of claim 6 and 9 since it contains the sequence PQRCPSLRQAVQLTHQQQGQV and PQRCPSLRQAVQLTHQ (see bolded in the above sequence). This meets the limitation of the claim 12 since the peptide QGPGRQPDFQRCGQQLRNISPP is the beginning portion of the prior art peptide (see italicized

in the above sequence). The reference discloses that the peptide has coagulation activity (see page 16 and antimicrobial activity (see page 17). This meets the limitation of the "use of " claims.

While the prior art peptide is longer than the claimed sequences, it still meets the limitation of the claims since the claims are open-ended and does not exclude additional, unrecited elements. Note that MPEP recognizes the transitional phrase "consisting of" to exclude any element, step, or ingredient not specified in the claim (see MPEP 2111.03).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can normally be reached on (571) 272-0562. The fax phone number of this group is (571)-273-8300.

/Anish Gupta/
Primary Examiner, Art Unit 1654